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October 28, 2002

OWNSEND and TOWNSEND and CREW LLP

**PATENT** 

Attorney Docket No. 16303-008110

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Angela M.I. Lam, et al.

Application No.: 09/839,707

Filed: April 20, 2001

METHODS OF ENHANCING SPLP-MEDIATED TRANSFECTION USING

ENDOSOMAL MEMBRANE

Assistant Commissioner for Patents

DESTABILIZERS

Washington, D.C. 20231

Examiner: Dave Nguyen

Art Unit: 1632

RESPONSE TO RESTRICTION

**REQUIREMENT** 

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Sir:

In response to the Restriction Requirement mailed August 27, 2002, Applicants elect, with traverse, to prosecute the claims of Group I, claims 1-63 and 68, drawn to a nucleic acid-lipid particle composition of claim 1, and a nucleic acid delivery method employing the nucleic acid-lipid particle composition of claim 1. Applicants' election is made with traverse as examination of the subject matter recited in the claims of Groups I and II would not place a substantially greater burden on the Examiner.

Further, in response to the Species Elections set forth by the Examiner, Applicants elect the following species:

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(a) the species wherein said endosomal membrane destabilizer is Ca<sup>++</sup> ion (claim 4), and the concentration of Ca<sup>++</sup> ion is from about 1 mM to about 20 mM (claim 6);

- (b) the species wherein said cationic lipid is DODAC (claims 8 and 39);
- (c) the species wherein said noncationic lipid is DOPE (claims 10 and 41);
- (d) the species wherein the conjugated lipid that inhibits aggregation of particles has the formula: A-W-Y, wherein W is PEG (claims 13, 17, 44 and 48), A is a diacylglycerolyl moiety (claims 16 and 47), and Y is lysine (claims 15 and 46);
- (e) the species wherein the conjugated lipid that inhibits aggregation of particles has the formula:

$$A - \left(CH_2 - CH_2 - O)_n - Z\right) - Y$$

II

wherein A is a diacylglycerolyl moiety having two fatty acyl chains, wherein each acyl chain is a saturated C-18 carbon chain (claims 20, 23, 24, 26, 51, 54, 55 and 57); Y is a cationic group having 4 lysine residues (claims 20, 23, 25, 26, 51, 54, 56 and 57); X is a phosphoethanolamino (claims 20, 21, 23, 51, 52 and 54); and Z is NR, wherein R is hydrogen (claims 20, 22, 23, 51, 52 and 54);

- (f) the species wherein the conjugated lipid that inhibits aggregation of particles is a PEG-ceramide (claims 27, 28, 58 and 59); and
  - · (g) the species wherein the nucleic acid is a plasmid (claims 32 and 63).

As stated in MPEP § 809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141."

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If the Examiner has any questions regarding Applicants' election, or if the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (925) 472-5000.

Respectfully submitted,

Eugema Garrett Wackows

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